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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,455	05/08/2001	Y Tom Tang	PF-0634 USN	4335

27904 7590 05/29/2003

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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 05/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

09/831,455

Applicant(s)

TANG ET AL.

Examiner

David J. Steadman

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-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_ .
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_ .
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ . | 6) <input type="checkbox"/> Other: ____ .                                   |

## **DETAILED ACTION**

### ***Status of the Application***

**[1]** Claims 1-20 are pending in the application.

**[2]** The specification is objected to as applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

### ***Lack of Unity***

**[3]** Lack of unity is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:

**Groups I-XV**, claims 1, 2, 14, 15, and 19, drawn to the special technical feature of a purified polypeptide, the first claimed method of making a polypeptide, a pharmaceutical composition comprising a polypeptide, and the first claimed method of use, i.e., a method for treating or preventing a disorder. Group I recites SEQ ID NO:1, Group II recites SEQ ID NO:3, Group III recites SEQ ID NO:4, Group IV recites SEQ ID NO:5, Group V recites SEQ ID NO:6, Group VI recites SEQ ID NO:7, Group VII recites SEQ ID NO:8, Group VIII recites SEQ ID NO:9, Group IX recites SEQ ID NO:10, Group X recites SEQ ID NO:11, Group XI recites SEQ ID NO:12, Group XII recites SEQ ID NO:13, Group XIII recites SEQ ID NO:14, Group XIV recites SEQ ID NO:15, and Group XV recites SEQ ID NO:16.

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**Groups XVI-XXXI**, claims 3-13, drawn to the special technical feature of an isolated and purified polynucleotide, the first claimed method of use, i.e., a method for detecting a polynucleotide, an expression vector, and a host cell. Group XVI recites a nucleic acid encoding SEQ ID NO:1 including SEQ ID NO:17, Group XVII recites a nucleic acid encoding SEQ ID NO:3 including SEQ ID NO:19, Group XVIII recites a nucleic acid encoding SEQ ID NO:4 including SEQ ID NO:20, Group XIX recites a nucleic acid encoding SEQ ID NO:5 including SEQ ID NO:21, Group XX recites a nucleic acid encoding SEQ ID NO:6 including SEQ ID NO:22, Group XXI recites a nucleic acid encoding SEQ ID NO:7 including SEQ ID NO:23, Group XXII recites a nucleic acid encoding SEQ ID NO:8 including SEQ ID NO:24, Group XXIII recites a nucleic acid encoding SEQ ID NO:9 including SEQ ID NO:25, Group XXIV recites a nucleic acid encoding SEQ ID NO:10 including SEQ ID NO:26, Group XXV recites a nucleic acid encoding SEQ ID NO:11 including SEQ ID NO:27, Group XXVI recites a nucleic acid encoding SEQ ID NO:12 including SEQ ID NO:28, Group XXVII recites a nucleic acid encoding SEQ ID NO:13 including SEQ ID NO:29, Group XXVIII recites a nucleic acid encoding SEQ ID NO:14 including SEQ ID NO:30, Group XXIX recites a nucleic acid encoding SEQ ID NO:15 including SEQ ID NO:31, Group XXX recites a nucleic acid encoding SEQ ID NO:16 including SEQ ID NO:32, and Group XXXI recites SEQ ID NO:18.

**Groups XXXII-XLVI**, claim 16, drawn to the special technical feature of a purified antibody that binds to a polypeptide. Group XXXII recites an antibody that binds SEQ ID NO:1, Group XXIII recites an antibody that binds SEQ ID NO:3, Group XXXIV recites an antibody that binds SEQ ID NO:4, Group XXXV recites an antibody that binds SEQ ID NO:5, Group XXXVI recites an antibody that binds SEQ ID NO:6, Group XXXVII recites an antibody that binds SEQ ID NO:7, Group XXXVIII recites an antibody that binds SEQ ID NO:8, Group XXXIX recites an antibody that binds SEQ ID NO:9, Group XL recites an antibody that binds SEQ ID NO:10, Group XLI recites an antibody that binds SEQ ID NO:11, Group XLII recites an antibody that binds SEQ ID NO:12, Group XLIII recites an antibody that binds SEQ ID NO:13, Group XLIV recites an antibody that binds SEQ ID NO:14, Group XLV recites an antibody that binds SEQ ID NO:15, and Group XLVI recites an antibody that binds SEQ ID NO:16.

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**Groups XLVII-LXI**, claim 17, drawn to the special technical feature of a purified agonist of a polypeptide. Group XLVII recites an agonist of SEQ ID NO:1, Group XLVIII recites an agonist of SEQ ID NO:3, Group XLIX recites an agonist of SEQ ID NO:4, Group L recites an agonist of SEQ ID NO:5, Group LI recites an agonist of SEQ ID NO:6, Group LII recites an agonist of SEQ ID NO:7, Group LIII recites an agonist of SEQ ID NO:8, Group LIV recites an agonist of SEQ ID NO:9, Group LV recites an agonist of SEQ ID NO:10, Group LVI recites an agonist of SEQ ID NO:11, Group LVII recites an agonist of SEQ ID NO:12, Group LVIII recites an agonist of SEQ ID NO:13, Group LIX recites an agonist of SEQ ID NO:14, Group LX recites an agonist of SEQ ID NO:15, and Group LXI recites an agonist of SEQ ID NO:16.

**Groups LXII-LXXVI**, claims 18 and 20, drawn to the special technical feature of a purified antagonist of a polypeptide and the first claimed method of use, i.e., a method for treating or preventing a disorder. Group LXII recites an antagonist of SEQ ID NO:1, Group LXIII recites an antagonist of SEQ ID NO:3, Group LXIV recites an antagonist of SEQ ID NO:4, Group LXV recites an antagonist of SEQ ID NO:5, Group LXVI recites an antagonist of SEQ ID NO:6, Group LXVII recites an antagonist of SEQ ID NO:7, Group LXVIII recites an antagonist of SEQ ID NO:8, Group LXIX recites an antagonist of SEQ ID NO:9, Group LXX recites an antagonist of SEQ ID NO:10, Group LXXI recites an antagonist of SEQ ID NO:11, Group LXXII recites an antagonist of SEQ ID NO:12, Group LXXIII recites an antagonist of SEQ ID NO:13, Group LXXIV recites an antagonist of SEQ ID NO:14, Group LXXV recites an antagonist of SEQ ID NO:15, and Group LXXVI recites an antagonist of SEQ ID NO:16.

**[4]** The inventions listed as Groups I-LXXVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

**[5]** According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(A) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common property or activity. The polypeptides of Groups I-XV lack common structure, the polynucleotides of Groups XVI-XXXI lack common structure, the antibodies of Groups XXXII-XLVI lack common structure, the agonists of Groups

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XLVII-LXI lack common structure, and the antagonists of Groups LXII-LXXVI lack common structure and thus, the molecules share no special technical feature.

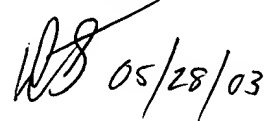
**[6]** According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-LXXXVI do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of Groups I-XV is a purified polypeptide and the technical feature of Groups XVI-XXXI is an isolated and purified polynucleotide. The polypeptides of Groups I-XV and the polynucleotides of Groups XVI-XXXI are shown to lack novelty or inventive step because these technical features are not contributions over the prior art as claims drawn to polypeptides comprising fragments of the polypeptides (e.g., claim 1) and the respective encoding nucleic acids (e.g., claim 9) read on *any* polypeptide or *any* encoding nucleic acid. Thus, Groups I-LXXXVI share no special technical feature.

**[7]** Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

**[8]** Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for Group 1600 is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.  
Patent Examiner  
Art Unit 1652

 05/28/03